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# Comparative safety of endovascular and open surgical repair of abdominal aortic aneurysms in low-risk male patients

Jeffrey J. Siracuse, MD, Heather L. Gill, MD, Ashley R. Graham, MD, Darren B. Schneider, MD, Peter H. Connolly, MD, Art Sedrakyan, MD, PhD, and Andrew J. Meltzer, MD, *New York, NY*

**Objective:** The prevalence of significant comorbidities among patients with abdominal aortic aneurysms (AAAs) has contributed to widespread enthusiasm for endovascular AAA repair (EVAR). However, the advantages of EVAR in patients at low risk for open surgical repair (OSR) remain unclear. The objective of this study was to assess perioperative outcomes of EVAR and OSR in low-risk patients.

**Methods:** Patients undergoing EVAR and OSR for infrarenal AAAs were identified in the 2007 to 2010 National Surgical Quality Improvement Program data sets. AAA-specific risk stratification, by the Medicare aneurysm scoring system, was used to create matched low-risk (score <3) cohorts. Perioperative morbidity and mortality were assessed by crude comparisons of matched groups and regression models.

**Results:** Of 11,753 elective patients undergoing EVAR, 4339 (37%) were deemed low risk (score <3). A matched cohort of 1576 low-risk patients was developed from a total of 3804 (41%) undergoing OSR. The low-risk cohorts included only male patients and those <75 years of age, without significant cardiac, pulmonary, or vascular comorbidities. Mean age in both low-risk groups was  $67 \pm 6$  years ( $P = \text{NS}$ ). EVAR patients had higher rates of obesity (40% vs 33%;  $P < .001$ ), diabetes (16% vs 13%;  $P = .005$ ), history of cardiac intervention (24% vs 19%;  $P < .001$ ), cardiac surgery (23% vs 20%;  $P = .02$ ), steroid use (4% vs 2%;  $P = .002$ ), and bleeding disorders/anticoagulation (9% vs 6%;  $P = .001$ ) compared with OSR patients. There were no other differences between the matched cohorts. EVAR was associated with reduced 30-day mortality (0.5% vs 1.5%;  $P < .01$ ) and reduced rates of major complications, including the following: sepsis (0.7% vs 3.2%;  $P < .01$ ), unplanned intubation (1.0 vs 5.4%;  $P < .001$ ), pneumonia (0.8% vs 6.1%;  $P < .001$ ), acute renal failure (0.4% vs 2.7%;  $P < .001$ ), and early reoperation (3.7% vs 6.0%;  $P < .001$ ). Furthermore, EVAR was associated with reduced perioperative morbidity across organ systems, including venous thromboembolism (0.1% vs 0.3%;  $P = .001$ ), transfusion requirement of more than 4 units (2.0% vs 13.0%;  $P < .001$ ), cardiac arrest (0.2 vs 0.8;  $P = .001$ ), neurologic deficits (0.2% vs 0.5%;  $P = .032$ ), and urinary tract infections (1.2% vs 2%;  $P = .02$ ).

**Conclusions:** Our results demonstrate that even among those male patients at low risk for OSR on the basis of comorbidities, EVAR is associated with reduced perioperative mortality and major complications. Whereas clinical decisions must account for safety and long-term effectiveness, the short-term benefit of EVAR is evident even among male patients at the lowest risk for OSR. (*J Vasc Surg* 2014;60:1154-8.)

Since 2006, endovascular repair (EVAR) of abdominal aortic aneurysms (AAAs) has outpaced open surgical repair (OSR), with more than 70% of AAAs now repaired by EVAR.<sup>1,2</sup> Despite persistent concerns about long-term durability, enthusiasm for EVAR is driven by the reduced early morbidity associated with this less invasive technique, particularly in light of the high prevalence of significant comorbidities among patients with AAA. Overall, EVAR

has been associated with improved early outcomes in comparison with OSR.<sup>3,4</sup> Furthermore, on a population level, the increased use of EVAR has been associated with lower short-term AAA-related mortality and fewer aneurysms presenting with rupture.<sup>1</sup> High-risk and elderly patients, in particular, have been shown to benefit with EVAR compared with OSR in regard to perioperative complications and mortality.<sup>2-6</sup>

However, the benefit of EVAR over OSR in patients who are at low risk for perioperative morbidity and mortality remains unclear. Whereas the superiority of minimally invasive treatments such as EVAR may provide an obvious short-term benefit for high-risk patients, vascular specialists continue to debate the appropriateness of EVAR in patients who are suitable candidates for OSR who could be expected to tolerate OSR. In fact, low-risk patients may be preferentially offered open repair, particularly if vascular specialists believe the favorable durability of OSR overshadows any short-term benefit of EVAR—if it even exists—in patients at low risk for perioperative complications.<sup>2,7-9</sup> To address these considerations, we used the American College of Surgeons National Surgical Quality

From the Division of Vascular and Endovascular Surgery, New York—Presbyterian Hospital, Weill Cornell Medical College.

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Reprint requests: Jeffrey J. Siracuse, MD, New York—Presbyterian Hospital, Weill Cornell Medical College, 525 E 68 St, New York, NY 10021 (e-mail: [Jes9061@nyp.org](mailto:Jes9061@nyp.org)).

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**Table I.** Medicare aneurysm scoring system<sup>10</sup>

<i>Risk factor</i>	<i>Score</i>
Age >80 years	11
Age 76-80 years	6
Age 71-75 years	1
Female	4
ESRD	9
CRI, no dialysis	7
CHF	6
PVD or CBVD	3

CBVD, Cerebrovascular disease; CHF, congestive heart failure; CRI, chronic renal insufficiency; ESRD, end-stage renal disease; PVD, peripheral vascular disease.

High risk, >11; moderate risk, 3-11; low risk, <3.

Improvement Program (ACS NSQIP) data to compare perioperative outcomes of EVAR with those of OSR in low-risk patients. We hypothesized that the perceived short-term benefits of EVAR vs OSR would be demonstrable in this low-risk cohort.

## METHODS

Patients undergoing elective EVAR and OSR for infrarenal AAAs were identified in the 2007 to 2010 NSQIP data sets. AAA-specific risk stratification, by the Medicare aneurysm scoring system, was used to create matched low-risk cohorts (Table I).<sup>10</sup> Institutional Review Board approval was obtained and patient consent was waived.

**Medicare aneurysm scoring system.** The Medicare aneurysm score was developed as a risk prediction tool for perioperative mortality specific to AAA repair. Derived from Medicare data of all patients undergoing both intact EVAR and OSR of AAA, the scoring system facilitates risk prediction based on preoperative characteristics applicable to patients undergoing both EVAR and OSR.<sup>10</sup> Variables included in the model are age and gender and the presence of congestive heart failure, peripheral vascular disease, chronic renal insufficiency, and cerebrovascular disease; points are assigned on the basis of the degree of influence on the risk. After assignment of a cumulative point score, patients may be risk stratified into low-, moderate-, and high-risk categories for perioperative mortality (Table I). Female gender in the model is assigned a score of 4; therefore, no female patients are low risk (score <3). Analysis of the low-risk groups contains only male patients.

**ACS NSQIP.** The ACS NSQIP program is a prospective, multicenter database with risk-adjusted outcomes for quality improvements. Details pertaining to data gathering, sampling, and structure of the participant use files have been previously described.<sup>10-12</sup> The ACS NSQIP includes perioperative data with >135 variables, including patient characteristics, preoperative risk factors, intraoperative variables, and 30-day postoperative complications and mortality for specified surgical procedures.

**Database development and scoring.** All patients undergoing infrarenal AAA repair without visceral or renal

involvement by EVAR or OSR were identified by the ACS NSQIP during a 4-year period from 2007 to 2010. Infrarenal AAA repairs were identified by Current Procedural Terminology (CPT, American Medical Association, Chicago, IL) codes 34800, 34802, 34803, 34804, 34805, 35081, and 35102. Patients with additional CPT codes suggesting more complex aneurysms with visceral involvement (35091, 35092) or with concomitant bypass grafts to the renal or visceral vessels (35531, 35560, 35535, 35536, 35631, 35632, 35633, 35634, 35636) were excluded from the analysis.

Demographic variables examined included age, sex, race, and smoking history. Preoperative functional status (independent, partially dependent, and totally dependent) assesses the patient's ability to perform activities of daily living before the operation. Medical conditions included diabetes mellitus, severe chronic obstructive pulmonary disease, congestive heart failure, hypertension, peripheral vascular disease requiring prior revascularization or amputation, altered mental status, prior steroid use, bleeding disorders/chronic anticoagulation, hemodialysis dependence, prior percutaneous coronary intervention, prior cardiac surgery, current angina or myocardial infarction 6 months before surgery, prior stroke with or without deficits, do not resuscitate status, and presence of a wound or infection. Specific details of the aortic aneurysm, aside from visceral involvement, are not variables in the NSQIP.

Bivariate analysis was performed to compare outcomes between EVAR and OSR. Categorical variables were compared by Pearson  $\chi^2$  tests, and distributions of continuous variables were compared by Wilcoxon rank sum tests. To facilitate analysis specifically of low-risk patients, NSQIP-captured variables were used to derive the Medicare aneurysm score for each patient, and only those in the lowest risk group for perioperative mortality (score <3) were included in the analysis.

## RESULTS

There were 11,753 patients who underwent elective endovascular repair and 3804 patients who underwent open repair of infrarenal AAA without visceral involvement from 2007 to 2010. Of these, 4339 patients (37%) undergoing EVAR were low risk by the Medicare aneurysm scoring system, whereas 1576 patients (41%) undergoing OSR were low risk. These cohorts included only men, those aged <75 years, and those without a history of congestive heart failure, chronic renal insufficiency, peripheral vascular disease, or cerebrovascular disease. Mean age in both low-risk groups was  $67 \pm 6$  years. Comorbidities in each group are listed in Table II. These low-risk male EVAR patients had a higher rate of comorbidities overall, specifically obesity, previous coronary disease, steroid use, and bleeding disorders/chronic anticoagulation.

EVAR was associated with lower 30-day mortality (0.5% vs 1.5%;  $P < .01$ ) compared with OSR. Moreover, EVAR was associated with reduced perioperative morbidity across organ systems. These included lower pulmonary,

**Table II.** Patient characteristics and comorbidities

<i>Covariate</i>	<i>Total, No. (%)</i>	<i>EVAR, No. (%)</i>	<i>OSR, No. (%)</i>	<i>P value</i>
Total	5527	4068	1459	N/A
Nonwhite	780 (14)	561 (14)	219 (21)	.25
White	4747 (86)	3507 (86)	1240 (79)	
Body mass index				<.001
Normal	1137 (21)	760 (19)	377 (26)	
Underweight	68 (1)	46 (1)	22 (2)	
Overweight	2135 (39)	1572 (39)	563 (39)	
Obese	2119 (38)	1637 (40)	482 (33)	
Presurgery functional health status				.23
Independent	5433 (99)	4005 (98)	1428 (98)	
Partial dependence	80 (1)	55 (1)	25 (2)	
Total dependence	14 (<1)	8 (<1)	6 (<1)	
Diabetes (–)	4678 (85)	3410 (84)	1268 (87)	.05
Diabetes (+)	849 (15)	658 (16)	191 (13)	
Steroid use (–)	5351 (97)	3921 (96)	1430 (98)	.002
Steroid use (+)	176 (3)	147 (4)	29 (2)	
Weight loss (–)	5472 (99)	4029 (99)	1443 (99)	.65
Weight loss (+)	55 (1)	39 (1)	16 (1)	
Bleeding disorder/anticoagulation (–)	5088 (92)	3715 (91)	1375 (94)	.001
Bleeding disorder/anticoagulation (+)	439 (8)	353 (9)	84 (6)	
COPD (–)	4545 (82)	3340 (83)	1205 (82)	.68
COPD (+)	982 (18)	728 (17)	254 (18)	
Prior PCI (–)	4257 (77)	3078 (76)	1179 (81)	<.001
Prior PCI (+)	1270 (23)	990 (24)	280 (19)	
Prior cardiac surgery (–)	4318 (78)	3147 (77)	1171 (80)	.021
Prior cardiac surgery (+)	1209 (22)	921 (23)	288 (20)	
Recent MI (–)	5467 (99)	4024 (99)	1443 (99)	.96
Recent MI (+)	60 (1)	44 (1)	16 (1)	
Hypertension (–)	1248 (23)	925 (23)	323 (22)	.64
Hypertension (+)	4279 (77)	3143 (77)	1136 (78)	

COPD, Chronic obstructive pulmonary disease; EVAR, endovascular aneurysm repair; N/A, not applicable; MI, myocardial infarction; OSR, open surgical repair; PCI, percutaneous coronary intervention.

**Table III.** Systemic complications

<i>Complications</i>	<i>Total, No. (%)</i>	<i>EVAR, No. (%)</i>	<i>OSR, No. (%)</i>	<i>P value</i>
Total	5527	4068	1459	N/A
Mortality, 30-day	46 (0.8)	24 (0.5)	22 (1.5)	.001
Return to the OR within 30 days	239 (4.3)	151 (3.7)	88 (6.0)	<.001
Deep venous thrombosis	30 (0.5)	14 (0.3)	16 (1.1)	.001
Graft complications	35 (0.6)	29 (0.7)	6 (0.4)	.21
Postoperative blood transfusion	28 (0.5)	8 (0.2)	20 (1.4)	<.001
Myocardial infarction	39 (0.7)	18 (0.4)	21 (1.4)	<.001
Cardiac arrest	20 (0.4)	8 (0.2)	12 (0.8)	<.001
Neurologic deficit	16 (0.3)	8 (0.2)	8 (0.5)	.032
Stroke	8 (0.1)	5 (0.1)	3 (0.2)	.48
Acute renal failure	54 (1.0)	15 (0.4)	39 (2.7)	<.001
Postoperative intubation >48 hours	130 (2.4)	26 (0.6)	104 (7.1)	<.001
Pulmonary embolism	16 (0.3)	10 (0.2)	6 (0.4)	.31
Unplanned reintubation	120 (2.2)	41 (0.1)	79 (5.4)	<.001

EVAR, Endovascular aneurysm repair; N/A, not applicable; OR, operating room; OSR, open surgical repair.

cardiac, neurologic, and renal complications (Table III). Infectious and wound complications were lower in EVAR compared with OSR, with less pneumonia, sepsis, septic shock, urinary tract infections, and wound dehiscence (Table IV). There were also fewer reoperations within 30 days in the EVAR group. There was no difference seen for graft complications, stroke, pulmonary embolism, or superficial or deep surgical site infections. No

complications were more prevalent in the EVAR group. Median length of stay in the EVAR group was 1 day compared with 6 days with OSR ( $P < .001$ ).

## DISCUSSION

Our results demonstrate that EVAR is associated with reduced perioperative mortality and major morbidity compared with OSR in low-risk male patients.

**Table IV.** Infectious complications

Complications	Total, No. (%)	EVAR, No. (%)	OSR, No. (%)	P value
Superficial SSI	82 (1.5)	56 (1.4)	26 (1.8)	.27
Deep SSI	26 (0.5)	9 (0.2)	17 (1.2)	.341
Organ space SSI	12 (0.2)	4 (0.1)	8 (0.5)	.002
Wound dehiscence	34 (0.6)	8 (0.2)	26 (1.8)	<.001
Pneumonia	122 (2.2)	33 (0.8)	89 (6.1)	<.001
Urinary tract infection	76 (1.4)	47 (1.2)	29 (2.0)	.02
Sepsis	74 (1.3)	27 (0.7)	47 (3.2)	<.001
Septic shock	51 (0.9)	35 (0.9)	16 (1.1)	<.001

EVAR, Endovascular aneurysm repair; OSR, open surgical repair; SSI, surgical site infection.

Perioperative mortality was threefold increased with open repair in this low-risk population. Complications that were more common with OSR included multiple organ systems: pulmonary, cardiac, renal, hematologic, and genitourinary. Perioperative unplanned return to the operating room was also significantly higher in the OSR group, as was median postoperative length of stay. Infectious complications including pneumonia, urinary tract infection, sepsis, and septic shock were also higher with OSR. These findings are particularly striking when one considers that despite an effort to match cohorts by the Medicare aneurysm scoring system, patients in the EVAR group had higher rates of diabetes, obesity, steroid use, coagulation disorders/chronic anticoagulation, and previous percutaneous and open cardiac interventions compared with patients in the OSR group. This finding reaffirms the superior short-term outcomes of EVAR. The superior safety profile of EVAR, compared with OSR, has previously been established for the overall population.<sup>2,3</sup> This benefit has been particularly shown to extend to high-risk patients and those with advanced age.<sup>2,3</sup> Most vascular specialists would agree that for patients at increased risk for adverse perioperative events, the favorable safety profile of EVAR supersedes the durability of OSR.<sup>2,3</sup> The minimally invasive nature of EVAR led to its rapid adoption and dissemination. Whereas the benefit of EVAR in high-risk patients is self-evident, the optimal management of patients with AAA who are at “low risk” for OSR remained controversial, and it remained unclear if EVAR was justifiable—on the grounds of favorable short-term outcomes—in patients at low risk for OSR. We used the NSQIP database to assess early outcomes and perioperative morbidity and mortality because the benefit of EVAR hinges on favorable perioperative outcomes.

The objective of this retrospective study was not to assess long-term outcomes between the two treatment modalities. The long-term durability of OSR is beyond repute, and even endovascular enthusiasts must concede that there are insufficient data with the current incarnation of devices for EVAR to compare with the decades of experience with OSR. As the benefit of EVAR remains perioperative outcomes, understanding of short-term outcomes has a critical role in clinical decision making.<sup>2,5,11</sup> Clinical decisions must account for the long-term safety and effectiveness of EVAR compared with OSR; these need to be

evaluated on the basis of the individual case and will need to be re-evaluated as the technology changes. Long-term comparison of EVAR with OSR remains unclear. There is variation in the literature; some studies show improved long-term survival with EVAR compared with OSR despite treatment of an overall healthier, younger population with OSR, and others show equal long-term survival.<sup>13-17</sup> Data supporting long-term benefit and durability of EVAR include the Open vs Endovascular Repair (OVER) trial, which showed no difference in overall survival at 9 years with an increased long-term survival benefit in patients younger than 70 years. However, there were more aneurysm-related deaths in the EVAR group, but overall numbers were low.<sup>13</sup> The goal of this study was not to assess this but rather to address the perioperative outcomes. The improved perioperative outcomes with EVAR in the low-risk patient population seen here need to be balanced with the long-term risks for reintervention and durability of the repair. However, we have demonstrated that it is not appropriate simply to assume that the perioperative risks are equal between EVAR and OSR for the lowest risk male patients.

Limitations of this study include those inherent to use of a large national database. However, one of the main advantages of the NSQIP database is that it offers independent adjudication of 30-day outcomes by an impartial party, namely, a trained clinical nurse—reviewer, that has been previously validated. In addition, only those patients who were deemed “fit” by vascular surgeons were included in the database, leading to an inherent selection bias. NSQIP does not provide us with long-term outcomes, although that is not the objective of this paper. Also, NSQIP does not include every patient at every participating center; however, it randomly samples patients to obtain an accurate assessment. Another limitation is that we cannot stratify by region or center to take into account volume-outcome relationships. Because the diagnosis was based on CPT codes, despite efforts to exclude those cases with visceral segment involvement, aneurysm characteristics other than important clinical parameters such as aneurysm size and clamp location cannot be ascertained from this data set. The Medicare aneurysm model assigns 4 points for female gender, and low risk was defined as <3 points (Table I).<sup>10</sup> No female patients are considered low risk in this model, and therefore a low-risk comparison

of OSR vs EVAR must omit female patients. This makes our analysis applicable only to male patients. Finally, the overall absolute rates of mortality and significant complications are low, raising the issue of effect size in a study such as this. However, it is noteworthy that in many cases, the difference not only was statistically significant but represents a several-fold difference between the two groups.

## CONCLUSIONS

Our results from a national registry demonstrate that even among those patients at lowest risk in regard to their comorbidities for OSR, EVAR is associated with reduced perioperative mortality and major complications. Whereas clinical decisions must account for safety and long-term effectiveness, the short-term benefit of EVAR in low-risk male patients is evident compared with OSR.

## AUTHOR CONTRIBUTIONS

Conception and design: JS, AM, AS

Analysis and interpretation: JS, HG, AG, DS, PC, AS, AM

Data collection: JS, AM

Writing the article: JS, AM

Critical revision of the article: JS, HG, AG, DS, PC, AS, AM

Final approval of the article: JS, HG, AG, DS, PC, AS, AM

Statistical analysis: JS, AG, AM

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Overall responsibility: AM

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